# Medical Reserve Corps

COVID-19 Testing Operations Overview
August 21, 2021





#### Presenters:

Brooke Rossheim, MD, MPH VDH Public Health Physician Specialist

Suzie Trotter, RN, BSN, MA VDH Covid-19 Testing Project Manager









COVID-19 Point-of-Care Testing August 21, 2021 Brooke Rossheim, MD, MPH

## A brief history of SARS-CoV-2 testing

- In 2020, main focus was on Covid-19 diagnostic testing using molecular (nucleic acid amplification or "NAA") tests = collect swab and send to outside lab
- PCR is just one type of molecular or NAA test
- FDA issued hundreds of Emergency Use Authorizations (EUAs) vast majority are for molecular tests. FDA continues to authorize tests under EUA
- In May & July 2020, Covid-19 antigen tests first became available and received FDA EUAs
- These "rapid tests" detect protein antigen around RNA of SARS-CoV-2 virus
- In August 2020, first lateral flow antigen test granted EUA by FDA = Abbott BinaxNOW COVID-19 Ag Card – uses a test strip, sample wicks its way along the strip – no need for analyzer device



## A brief history of SARS-CoV-2 testing – 2

- Multiple benefits of antigen testing:
  - Tests can be done at the point of care not a send out test
  - "CLIA waived" test = can do in office setting
  - Easy to perform
  - Results available in about 15 minutes

- Limitations of antigen testing:
  - Lack sensitivity of PCR testing, therefore, may have more false negative results compared to PCR



## A brief history of Covid-19 testing – 3

 In November 2020, FDA grants first EUA for a molecular test to be performed completely at home = the Lucira COVID-19 All-In-One Test Kit – a prescription item – person follows directions to complete test

 Abbott BinaxNOW COVID-19 Ag Card and Lucira molecular test help pave the way for "at-home" antigen and molecular tests. More diagnostic lab companies enter the "at-home" Covid-19 test market



## Point-of-care (POC) lab testing

- Lab testing completed where the patient is = specimen collected AND test performed onsite (examples of office-based tests: rapid influenza test, rapid strep test, and many others)
- Conventional lab testing = specimen taken from patient and sent to reference lab. Results reported back to ordering clinician
- POC tests can also be done at home (examples = urine pregnancy test, fingerstick glucose testing, and now Covid-19 tests). May be referred to as "self-administered tests"
- POC tests typically are easy to perform and CLIA-waived in office setting, need a CLIA certificate
- POC tests meant for home use are different than home specimen collection kits. Home collection kits = sample obtained at home and mailed to lab for testing.
- POC tests (whether at home or in office) have advantages and drawbacks



#### Types of COVID-19 Tests

#### **Covid-19 Molecular tests (example: PCR testing)**

- Used to diagnose current Covid-19 infections typically a nasal swab (or saliva) is collected as specimen
- Test detects genetic material from the virus itself
- Some tests are point-of-care

#### Covid-19 Antigen tests (example: Abbott BinaxNOW Covid-19 Antigen Card)

- Also used to diagnose current Covid-19 infections nasal swab typically obtained as specimen
- Test detects whether a SARS-CoV-2 viral protein is present or not
- Most antigen tests are point-of-care some meant for medical office use & some for home use
- Point of care tests provide results in 10-15 minutes, depending on the test

#### **Covid-19 antibody tests (also referred to as serology tests)**

- A blood test that looks for antibodies to the SARS-CoV-2 virus if antibodies are present, it MAY indicate
   PAST infection with Covid-19
- Antibody test NOT designed to diagnose current Covid-19
- HOWEVER, some important caveats: (1) POSSIBLE cross reactivity with other coronaviruses, (2) if antibody test is positive, does not indicate duration of immunity



### POC tests & general indications – self-administered tests

- Points below are generalities need to review package insert for specific test
- 1. Single antigen test (one point in time) = generally for symptomatic people within specific time frame after illness onset
  - Exception = Ellume (can be used for symptomatic or asymptomatic people)
- 2. Single molecular test (one point in time) = generally for symptomatic OR asymptomatic people, OR for people who have a reason to suspect COVID-19 infection or no reason to suspect COVID-19 infection
  - Can be used on anyone
  - Exception = Lucira COVID-19 All-In-One Test Kit (only for symptomatic people)
- 3. Serial antigen tests (2 tests done over a 2-3 day period) = for symptomatic or asymptomatic people, OR for people who have a reason to suspect COVID-19 infection or no reason to suspect COVID-19 infection
  - Can be used on anyone



### New over-the-counter (OTC) at-home antigen tests



# Over-the-counter COVID-19 rapid tests to be sent to major pharmacies this week

1 day ago









Store shelves at pharmacies across the county will soon be filled with affordable, quick, athome coronavirus test kits.



#### Self-administered point-of-care Covid-19 molecular tests as of 8/21/2021

Manufacturer	Test brand name	Date of original FDA EUA	Type of test	Rx or non- Rx test	What type of sample needs to be collected	Age range for test	Link to most recent FDA EUA letter	Test indication	Can test be mailed to person's home?	Additional information
Lucira Health Inc.	Lucira CHECK-IT COVID-19 Test Kit	4/9/2021	molecular	non-Rx	anterior nasal turbinate swab	age ≥ 2	www.fda.gov/m edia/147492/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	yes	For more information about test or to order, see www.lucirahealth.com. Smartphone or smart device not needed for test. Result available between 11 and 30 minutes.
Cue Health Inc.	Cue COVID-19 Test for Home and Over the Counter (OTC) Use	3/5/2021	molecular	non-Rx	anterior nares swab	age ≥ 2	www.fda.gov/m edia/146467/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	For more information, see https://www.cuehealth.com/what-is- cue/how-cue-detects-COVID-19. Smartphone needed to download app and use test. See list of compatible smartphones at www.cuehealth.com. Result in about 20 min.
Lucira Health Inc.	Lucira COVID-19 All- In-One Test Kit	11/17/2020	molecular	Rx	anterior nasal turbinate swab	age ≥ 14	www.fda.gov/m edia/143810/do wnload	individuals suspected of having COVID-19	no	For more information, see https://shop.lucirahealth.com/. Result available between 11 and 30 minutes.

-Cue Health test does require a smartphone to perform test



<sup>-</sup>Lucira tests do not require a smartphone to perform test. However, if person wants an official test result, this can be sent to phone.

#### Self-administered point-of-care Covid-19 antigen tests as of 8/21/2021

Manufacturer	Test brand name	Date of original FDA EUA	Type of test	Rx or non- Rx test	What type of sample needs to be collected	Age range for test	Link to most recent FDA EUA letter	Test indication	Can test be mailed to person's home?	Additional information
Access Bio, Inc.	CareStart COVID- 19 Antigen Home Test	8/2/2021	serial antigen testing	non-Rx	anterior nares swab	age ≥ 2	www.fda.gov/m edia/151245/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results must be read between 10-15 minutes after test started. According to the package labeling, a smartphone is needed; however, the FDA EUA letter states a smartphone can be used, but is not required. For more information, see https://accessbiodiagnostics.net
OraSure Technologies, Inc.	InteliSwab COVID- 19 Rapid Test Rx	6/4/2021	single antigen test	Rx	anterior nares swab	age ≥ 15	www.fda.gov/m edia/149904/do wnload	within first 7 days of symptom onset	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results in 30 minutes. For more info, see www.inteliswab.com.
OraSure Technologies, Inc.	InteliSwab COVID- 19 Rapid Test	6/4/2021	serial antigen testing	non-Rx	anterior nares swab	age ≥ 15	www.fda.gov/m edia/149908/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results in 30 minutes. For more info, see www.inteliswab.com.



#### Self-administered point-of-care Covid-19 antigen tests as of 8/21/2021

Manufacturer	Test brand name	Date of original FDA EUA	Type of test	Rx or non- Rx test	What type of sample needs to be collected	Age range for test	Link to most recent FDA EUA letter	Test indication	Can test be mailed to person's home?	Additional information
Abbott Diagnostics Scarborough Inc.	BinaxNOW COVID- 19 Antigen Self Test	4/1/2021	serial antigen testing	non-Rx	anterior nares swab	age ≥ 2	www.fda.gov/m edia/147251/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	yes	For more information, see www.abbott.com/BinaxNOW-Test- NAVICA-App.html. Test available at CVS, Walmart, and other stores or online. Result available in 15 minutes.
Quidel Corp.	QuickVue At-Home OTC COVID-19 Test	3/31/2021	serial antigen testing	non-Rx	anterior nares swab	age ≥ 2	www.fda.gov/m edia/147247/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	For more information, see https://quickvueathome.com/. Result in 10 minutes. Will be available at Walgreens in near future.
Abbott Diagnostics Scarborough Inc.	BinaxNOW COVID- 19 Ag Card 2 Home Test	3/31/2021	serial antigen testing	non-Rx	anterior nares swab	age≥2	www.fda.gov/m edia/147256/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	unknown	Unclear if test currently available. Test uses telehealth proctor. Must have a smart device or computer. Result available in 15 minutes.
Quidel Corp.	QuickVue At-Home COVID-19 Test	3/1/2021	single antigen test	Rx	anterior nares swab	age ≥ 8	www.fda.gov/m edia/146309/do wnload	within first 6 days after symptom onset	unknown	Unclear if test currently available. Result in 10 minutes.
Abbott Diagnostics Scarborough Inc.	BinaxNOW COVID- 19 Ag Card Home Test	12/16/2020	single antigen test	Rx	anterior nares swab	age ≥ 4	www.fda.gov/m edia/144576/do wnload	within first 7 days of symptom onset	yes	For more information, see www.abbott.com/BinaxNOW-Test- NAVICA-App.html. Available through www.emed.com. Uses telehealth proctor. Smart device or computer needed. Result in 15 minutes.
Ellume Limited	Ellume COVID-19 Home Test	12/15/2020	single antigen test	non-Rx	mid nasal turbinate swab	age ≥ 2	www.fda.gov/m edia/144457/do wnload	with or without COVID-19 symptoms or epi reason to suspect COVID-19	yes	For more information, see www.ellumecovidtest.com. Available at CVS Pharmacy or www.cvs.com. Result in 15 minutes. Smartphone and app required as part of test virginia persentation

### Common questions/issues about POC COVID-19 Tests

- Can a point-of-care molecular test be used as a confirmatory test for an antigen test? This is not the intended use of a POC molecular test; preference is to use an NAA test done in a high-complexity lab
- Are antigen tests accurate? Yes, but depends on the study. Greatest utility is in symptomatic people → if positive antigen test, no further testing needed. Overall, a small # of antigen tests will be recommended to have NAA test confirmation
- Are POC molecular tests as good as those done in high-complexity labs?
   Based on a study with one specific POC molecular test, no. But, varies by specific molecular POC test
- The specimen matters a great deal. The better the specimen = more accurate test result. See <a href="https://www.fda.gov/medical-devices/letters-health-care-providers/recommendations-providing-clear-instructions-patients-who-self-collect-anterior-nares-nasal-sample?utm\_medium=email&utm\_source=govdelivery</a>



#### COVID-19 Point-of-care tests – helpful websites

- FDA: In Vitro Diagnostics EUAs Antigen Diagnostic Tests for SARS-CoV-2 www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2
- FDA: In Vitro Diagnostics EUAs Molecular Diagnostic Tests for SARS-CoV-2 www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2
- FDA: In Vitro Diagnostics EUAs Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 <a href="www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2">www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2</a>
- VDH: Getting Started with COVID-19 Point of Care Antigen Testing: <a href="https://www.vdh.virginia.gov/content/uploads/sites/182/2021/03/Getting-Started-with-COVID-19-POC-Antigen-Testing.pdf">https://www.vdh.virginia.gov/content/uploads/sites/182/2021/03/Getting-Started-with-COVID-19-POC-Antigen-Testing.pdf</a>
- VDH Interim COVID-19 Antigen Testing Recommendations: https://www.vdh.virginia.gov/coronavirus/antigen-testing-recommendations/



# Thank you for your attention and for your service during this pandemic!

# Questions?

If you have questions later, please email

testinginfo@vdh.virginia.gov



#### Presenters:

#### Suzie Trotter, RN, BSN, MA VDH Covid-19 Testing Project Manager





## Community Testing Operations

- ★ What does COVID-19 Testing Event look like at the facility site?
  - PRIOR TO THE EVENT:
    - Planning
    - Logistics
    - Workforce
    - Training
  - AT THE EVENT:
    - Vendors/LHD/Volunteers will arrive approximately 1 hour early to review action plan for the testing that day and start the set-up process for: Registration, Specimen Collection location, Traffic control, etc.
    - MRC Volunteers will work with the Testing Lead at the location
    - Specimen Collection will occur and kits will be packaged and transported to the Lab by the LHD/Vendor or by commercial courier.
    - Results will be reported by the Lab/Vendor to the facility POC and LHD





## Community Testing Overview

- ★ As a Volunteer, you play a significant role for integrity and reliability of the tests.
- ★ The tests modality will be chosen for the event but the integrity of the tests, the timeliness including proper test disposal are key factors for the success of these events.







A volunteer conducts a nasal swab test for Dr. Janice Underwood and Governor Northam at a testing site.

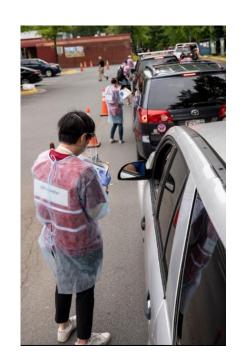
★ Community Testing Events are testing events open to local community members, which are organized by local health departments and community partners.







★ Community Testing Events vary in size - some LHDs choose to hold smaller (50 person) events each day in the same location, while other LHDs hold larger events (250 person) in different locations throughout their District.









★ Community Testing Events can be walk-up/drive-up and can require preregistration.









★ Community Testing Events are often planned and overseen by the Local Health Emergency Coordinator in each district.







# Testing Summary

- ⋆ Different Testing Platforms
- ⋆ Different Roles needed
- ⋆ Training Required
- Valuable Service to the community

#### Thank you for your service!





# Thank You

for choosing to volunteer with the Virginia Medical Reserve Corps!

YOU are the force multiplier that makes Virginia better prepared and resilient!



